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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/370,860 08/09/99 KADURUGAMUWA

J 7933.36US01

EXAMINER

HM22/0323

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ART UNIT	PAPER NUMBER

1645
DATE MAILED:

10
03/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/370,860

Applicant(s)
Kadurugamuwa et al.

Examiner
Robert A. Zeman

Group Art Unit
1645



☒ Responsive to communication(s) filed on Jan 8, 2001

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-17 is/are pending in the application.

Of the above, claim(s) 7-17 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-6 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-17 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Priority

The preliminary amendment contained within the transmittal letter is acknowledged. Consequently, Applicant's claim for benefit has been perfected. Claims 3-5 have been amended. Claims 1-6 are pending and currently under examination.

This application contains claims 7-17 drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Objections Withdrawn

The objection to claim 3 due to an improper abbreviation is withdrawn in light of the amendment thereto.

Claim Rejections Withdrawn

35 USC § 112

The rejection of claim 3 under 35 U.S.C. 112, second paragraph, for reciting improper Markush language is withdrawn in light of the amendment thereto.

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The rejection of claim 5 under 35 U.S.C. 112, second paragraph, for being vague and indefinite by using the phrase “a large membrane vesicle” is withdrawn in light of the amendment thereto.

Claim Rejections Maintained

35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 1 and 6 under 35 U.S.C. 112, second paragraph, for being vague and indefinite by using the phrase “carrier strain” is maintained for reasons of record.

Applicant argues:

1. The rejection does not establish that one of skill in the art, when reading the claims in light of the supporting specification, would not have been able to ascertain with a reasonable degree of precision the particular area set out and circumscribed by the claims.
2. The metes and bounds of the term “carrier strain” as it is used in claim 1 and 6 is described in the specification.

Applicants arguments have been fully considered and found to be non-persuasive. It is still unclear whether the carrier strains are bacterial in nature? viral? fungal? The specification is silent on this

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point. The portion of specification cited by Applicant merely shows that “carrier strain” may be bacterial in nature.

The rejection of claim 6 under 35 U.S.C. 112, second paragraph, for being vague and indefinite by using the phrase “against another infectious agent” is maintained for reasons of record. Applicant has failed to respond to this rejection.

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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The rejection of claims 1-6 under 35 U.S.C. 103(a) as being unpatentable over Hamstra et al. (WO 92/05194, IDS-6) in view of Viret et al. (EP 564 689, IDS-6) and Van Der Ley et al. (WO 94/08021, IDS-6) is maintained for reasons of record.

Applicant argues:

1. Hamstra et al. disclose acellular vaccines and teach away from the use of whole cell vaccines while the instant invention is drawn to cellular vaccines.
2. Viret et al. disclose a recombinant live vaccine that includes a bacterial strain that has been modified so it expresses at least one set of heterologous genes resulting in new immunogenic properties.
3. Viret et al. define carrier strain to mean "an attenuated bacterial strain carrying and expressing one or more foreign genetic determinants encoding protective antigens from a heterologous bacterium pathogenic for humans.
4. Van Der Ley et al. disclose an immunogenic molecule derived from a *Meningococcal* LPS. Van Der Ley et al. also disclose an outer membrane vesicle (OMV) provided with a group of polypeptides having at least the immunoactivity of outer membrane proteins (OMP) bound to a membrane, a polypeptide from the group of the outer membrane vesicles being a membrane anchored OMP or OMP fragment with a mutation in one of the surface loops.
5. Van Der Ley et al. made their OMV's utilizing the process disclosed by Fredriksen et al.

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6. Examiner has failed to provide motivation for combining the acellular vaccine system disclosed by Hamstra et al. and Van Der Ley et al. with the cellular system disclosed by Viret et al.

7. The aforementioned references do not disclose membrane vesicles characterized by having specific antigen associated with their surfaces, and containing specific enzymes, **which are native to the microorganism from which the membrane is derived.**

8. The outer membrane proteins disclosed by Van Der Ley et al. are extracted using the Fredriksen method. Treatment of the meningococci with EDTA results in membrane pieces not membrane vesicles as recited in the instant claims.

9. Even if the disclosures of Viret et al. and Van Der Lay et al. are properly combinable with Hamstra et al., they do not disclose a membrane vesicle from a microorganism.

Applicants arguments have been fully considered and have been found to be non-persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the vaccines of the instant invention are cellular-- point #1) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e. membrane vesicles characterized by having specific antigen associated with their surfaces, and containing specific enzymes, **which are native to the microorganism from which the membrane is**

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derived-- point #7), are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicants argument that Van Der Ley et al. do not disclose “membrane vesicles” as recited in the instant claims since the OMPs are extracted for meningococci using EDTA (points #5 and #8), it should be noted that the resulting “membrane pieces” have the same biological properties as the membrane vesicles of the instant invention. The fact they are derived by EDTA extraction does not preclude them from being membrane vesicles. Additionally, the disclosure of Van Der Ley et al. with regard to said membrane vesicles is applicable since the method of deriving said membrane vesicles is not a limitation set forth in the claims.

In response to applicant's argument that there is no suggestion to combine the references (point #6), the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). As stated in the previous Office Action, one would have been motivated to produce such a vaccine due to of the success of Hamstra et al. and Van Der Ley et al in using membrane vesicles as vaccine components and the teaching of Viret et al. which sets forth that antigens

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expressed on the surface of a carrier strain stimulate the immune system and elicit a protective immune response.

With regard to Applicant's argument that even if Van Der Ley and Viret et al. were combinable with Hamstra et al. it they do not disclose the limitation of "a membrane vesicle from a microorganism" (point #9), Applicant should note that Van Der Ley et al. disclose the use of outer membrane vesicles in combination with a group of polypeptides, with the immunoactivity of outer membrane proteins, bound to a membrane. Van Der Ley et al. further disclose vaccines comprising said membrane vesicles and lipopolysaccharides.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can be reached between the hours of 7:30 am and 4:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner can be reached at (703) 308-1032 or the examiner's supervisor, Lynette Smith, can be reached at (703)308-3909.



DONNA WORTMAN
PRIMARY EXAMINER

Robert A. Zeman

March 23, 2001